REMARKS

Reconsideration of this application is respectfully requested.

An information disclosure statement (IDS) was submitted on August 11, 2003. The PTO is requested to return an initialed copy of the IDS 1449 form indicating that the references cited in the IDS have been considered.

The rejection of claims 1 to 7, 9 to 11 and 13 to 21 as being obvious over Flank et al (U.S. Patent No. 4,838,865 – Flank) in view of Bullister et al (US Patent 6,171,253 – Bullister) and Crozafon et al (US Patent 6,272,930 – Crozafon) is traversed and has been overcome by amendment.

Several claims have been amended to recite the cartridge housing as supporting a loop of the blood passage that engages a blood pump. The cartridge housing also supports a pressure sensor.

The claims require the fluid passage through the pressure sensor to have an internal diameter that is substantially the same as the internal diameter of the blood passage to which the pressure sensor is coupled. By maintaining a constant diameter through the blood passage and pressure sensor, uniform flow of the blood is promoted. See specification at pages 8 to 9 ("the integrated sensors do not disturb the laminar blood flow inside the blood line since the internal diameter of the sensor element is the same of the blood tubing").

Several elements of the rejected claims are not disclosed or suggested by Flank, Bullister or Crozafon including (without limitation):

A cartridge housing supporting a tube loop, as is recited in claims 1 to 7, 9 to 11 and 13 to 21. Bullister and Crozafon do not disclose any housing. Flank discloses a cassette 1, 1a, that has an inlet 17 and an outlet 19 that connect to a pump loop segment 10. Flank teaches away from mounting a tube loop on the cartridge, as is recited in the claims. Similarly, claim 7 requires the tube loop to be fixed to the cartridge housing and engaging a pump raceway when the housing is latched into the pump device.

- A cartridge housing that latches into a recess of the pump device such that the tube loop engages the pump. (Claims 1 to 7 and 9 to 11). Flank shows in Figures 1 and 2 a cassette mounted to a flat face of the pump device.
- Two cartridge housings for a blood circuit, wherein one housing supports a tube loop for blood flow and the second housing supports a filter and a filtrate loop for a filtrate pump. (Claim 3, 4, 6 and 16 to 21). Flank shows a single cassette and thus teaches away from two cartridge housings for a blood circuit.
- Integrated pressure sensors on the cartridge housing(s) such that the flow path through the sensor is a uniform diameter with the blood passage fixed to the housing. 1 to 7, 9 to 11 and 13 to 21. This issue is discussed further below. Similarly, claim 5 requires a smooth tubular channel contiguous with the blood passage in the circuit;

Flank discloses a blood pressure sensor (15--shown in detail in Figure 15) that does not have a blood passage with a uniform diameter with the tubing. Flank teaches the blood sensor unit as having a container 101 that is substantially larger than the blood tubing (103). Accordingly, Flank does not disclose or suggest a blood pressure sensor having a diameter substantially the same as the diameter of the blood tubing in order to promote laminar blood flow through the blood tubing and pressure sensor. Accordingly, Flank et al do not anticipate claims 1 to 4, 7 and 9.

Flank does not disclose a continuous flow path as is recited. Tube segment 10 and 11 are not of similar diameter. Figure 3 of Flank shows a pressure measuring head 33 having a wide flow path when compared to tube 11.

Flank states that:

> In order to illustrate the function of the abovementioned pressure measuring head, reference is made to FIG. 15, which separately shows such a pressure measuring head 101 suck into a machine front 107, which corresponds to the front 2 of the monitor housing 3 shown in FIG. 1. Thus, in FIG. 15 there is shown a container 101 with an inlet 102 which, by means of tube 103 communicates with the medium whose pressure is to be measured. If a through-flowing medium is measured, the container 101 is, of course, also provided with an outlet. In its operating condition, container 101 is sunk into a cavity 105 in a machine component 106, which is fixed into a front plate 107, e.g. the front of a monitor housing for the control of haemodialysis or haemofiltration. On the machine component 106 there is fastened a pressure-sensitive element 108 by means of a further machine component 109. This component may, for example, be screwed on by means of bolt 110. The pressure-sensitive element 108 may, for example, be a piezoelectric pressure pick-up. Alternatively, it may comprise a wire strain pick-up or any other suitable pressure

> measuring or sensing element. With the help of duct 111 the cavity 105 can thus communicate with a source of vacuum (not shown). In this manner, a pressure-transmitting wall part 112 of container 101 is fastened by suction onto the pressure-sensitive element 108. The pressure-transmitting wall part 112 and the pressure-monitoring surface of the pressure sensitive element 108 are sealed against the surrounding atmosphere with the help of annular seals 113, 114 and 115. The last mentioned seal 115 is thus situated inside a lockwasher 116. Finally, electrical connections to the pressure-sensitive element are indicated by reference Numerals 117 and 118 in FIG. 15. [Flank, col. 8, lns. 24-57].

In view of the above quote, Flank does not teach that a pressure sensor is integral to the blood flow path. Flank describes an apparatus that does not include the pressure sensor as part of the cassette. It is a separate component and is not in liquid contact with the blood path. It uses a separate membrane 112 to avoid contact with blood and is integral to the dialysis housing monitor 3.

Flank teaches away from the claimed invention because:

1) The Flank pressure sensor system does not have a "sensor has a fluid passage having an internal diameter substantially the same as an internal diameter of the blood passage". Figure 4 of Flank shows the diameter 36a expanded to a tube straddling between 30a and 33a which is not a substantially the same diameter.
2) The pressure sensor described by Flank is not a component of the cassette, it is attached to the dialysis monitor. Flank does not show a cartridge housing having a pressure sensor.

Bullister teaches a pressure sensor in a blood tube, where the pressure sensor changes the internal diameter of the blood passage. Much of the disclosure in Bullister describes various ways of modifying the passage way in a blood tube to accommodate a pressure sensor. Bullister teaches away from maintaining a uniform diameter passage through a pressure sensor which matches the diameter of a blood tube, as is being done in the claimed invention.

As described in Bullister, the flow through passage uses a flexing diaphragm as stated but the pressure sensors are not in contact with blood. Figure 2 of Bullister shows that the blood passage is not of a substantially the same diameter. The system described by Bullister (cols. Line 41 to 51), works in accordance with a thin plate theory where the thickness of the flexing membrane 34 must be substantially thin with respect to the diameter of the flexing membrane 32. Bullister describes the thickness of the membrane to be 0.13 mm line 65 column 2 and that the diameter is 6.36 mm col. 3 line 53. Bullister describes how the diaphragm has to be flat to afford the necessary resolution required in col. 3 line 52 to line 63. Thus, Bullister teaches that his design is limited to having a large flat diaphragm to attain the necessary resolution.

Crozafon describes a fluid pressure sensor, but does not disclose a blood circuit cartridge. There is no suggestion in Crozafon to affix a pressure sensor to a disposable blood cartridge. Moreover, Crozafon and Bullister do not suggest that the cassette disclosed in Flank be modified to form the claimed invention.

The rejection of claims 8 and 12 as being obvious over Flank, Bullister, Crozafon and further in view of Savitz et al (US Patent 4,229,299 – Savitz) is traversed for the reasons stated above for independent claim 1.

Savitz et al does not teach a blood pressure sensor having a diameter substantially the same as the blood passages to which it is connected. Accordingly, the combination of Savitz, Flank, Crozafon and Bullister does not teach the claimed invention.

Savitz device does not include a description of the pressure sensor but indicates that it is part of the console. *"Located downstream from the negative pressure regulator/flow controller assembly 106 is negative pressure monitoring means 107. The monitoring means may suitably comprise a negative pressure sensor which is operatively connected to visual display means for indicating the magnitude of the negative pressure of the dialysate solution. The negative pressure sensor may also be operatively connected with the negative pressure adjustment means in assembly 106, whereby negative pressure of the dialysate solution may be maintained at a predetermined level."*

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

Respectfully submitted,

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